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10/591,098	07/18/2007	Anke Stabenau	66188NAT(50964)	6371
21874 7590 09/12/2011 EDWARDS ANGELL PALMER & DODGE LLP P.O. BOX 55874 BOSTON, MA 02205				
EXAMINER				
LOVE, TREVOR M				
ART UNIT		PAPER NUMBER		
1611				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/591,098

**Applicant(s)**

STABENAU ET AL.

**Examiner**

TREVOR LOVE

**Art Unit**

1611

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 June 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 1-22, 24, 26 and 29-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23, 25, 27, 28 and 38-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Acknowledgement is made to Applicant's response to the Non-Final Office Action mailed 01/27/2011, and Applicant's response to the additional requirement for Election/Restriction filed 06/17/2011.

Claims 1-60 are pending.

Applicant's election without traverse of swellable polymers, cellulose derivatives, and protein/peptide in the reply filed on 06/17/2011 is acknowledged. The election being made without traverse, is made Final.

Claims 23, 25, and 28 were amended in the response filed 01/27/2011.

Claims 40-56 were newly added in the response filed 01/27/2011.

Claims 40, 41, 43-45, 48, 49, and 51 were amended in the response filed 06/17/2011.

Claims 57-60 were newly added in the response filed 06/17/2011.

Claims 23, 25, 27, 28, and 38-60 are currently under consideration.

### **Withdrawn Rejection and/or Objections**

The rejection of claims 23, 25, 27, 28, 38 and 39 under 35 U.S.C. 103(a) as being unpatentable over Suverkrup et al (U.S. Patent number 6,228,381) is withdrawn in view of Applicant's amendments to said claims.

The provisional rejection of claims 38 and 39 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22-25, 27-36, 39,

and 43-45 of copending Application No. 11/661,726 in view of Suverkrup et al (U.S. Patent number 6,228,381, patent issued May 8, 2001).

**Maintained Rejections – new grounds for newly added claims**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 23, 25, 27, 28, 40, 42-45, 48, 49, 54, and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Suverkrup et al (U.S. Patent number 6,228,381, patent issued May 8, 2001).**

Suverkrup teaches a pharmaceutical composition formed as a xerogel wherein said xerogel is lyophilized (freeze-dried). Said composition comprises an active compound which is dissolved and applied drop-wise to the xerogel carrier. Said composition can be hydrated with, for example, lacrimal fluid. The release of said pharmaceutical is taught to take place slowly (see entire document, for instance, column 4, lines 28-48). Said composition can be placed on strips for contact with body parts (see entire document, for instance, column 5, lines 36-48). Said composition is taught as being sterile (see entire document, for instance, column 6, lines 1-4). Said composition can comprise multiple actives (see entire document, for instance, claim 1).

Said composition can further comprise components such as hydroxypropylcellulose (a cellulose derivative) and polyvinyl alcohol (a surfactant) (see entire document, for instance, column 5, lines 13-25 and claims 11 and 21).

*Response to Arguments*

Applicant argues in the remarks filed 01/27/2011 that Suverkrup teaches evenly distributing throughout the xerogel the active component (see remarks, page 12, second paragraph). Applicant further states that "This art method differs in several aspects from the method as claimed in the present application" (see remarks, page 12, second paragraph). Applicant's argument is not found persuasive. First, it is noted that Applicant has elected the product as the instant invention. As such, Applicant's arguments directed to method steps are pertinent only to the extent that said method steps impart a structural element or feature. It is noted that Applicant has not identified what types of structural limitations are imparted by the microdroplets, but rather indicates (instant specification page 3, lines 16-19) that the microdroplets simply do not substantially change the shape of the carrier. It is further noted that MPEP 2113 states that "product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps", and "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966

(Fed. Cir. 1985). It is noted that even if the active agent is distributed throughout the xerogel, it is noted that some of the active would be on different surfaces of said xerogel.

## **New Grounds of Rejection**

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 38, 39, 41, 46, 47, 50-53, and 58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suverkrup et al (U.S. Patent number 6,228,381, patent issued May 8, 2001) as applied to claims 23, 25, 27, 28, 40, 42-45, 48, 49, 54, and 57 above, and further in view of Becher (DE 19940241 translation attached and relied upon for citation – IDS reference).**

The teachings of Suverkrup are set forth above.

Suverkrup, while teaching that a second active can be present, fails to provide sufficient specificity, further, Suverkrup, while teaching the active present, fails to directly identify that the composition is applied only to the surface and in particular patterns on a particularly shaped carrier. These deficiencies are made up for by the teachings of Becher.

Becher teaches that printing an active composition onto a thin substrate, and particularly, onto a wafer (see entire document, for instance, page 3, second paragraph). Said process allows for at least two or more actives preparations with different ingredients to be applied to a substrate either at the same time, or in succession. Further, the applying is preferably in the form of a pattern and said patterns can be applied to different areas of the surface (See entire document, for instance, page

4, last two paragraphs and claim 5). Said compositions can be applied to one or both sides of a thin substrate (see entire document, for instance, page 7, claim 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the method of applying the active compositions of Becher for the composition of Suverkrup. One would have been motivated to do so since Becher teaches that the method of Becher allows for greater control of the amounts, thickness, and locations of the active ingredients. It also allows for layering of the actives. There would be a reasonable expectation of success since Suverkrup it teaching actives present, and Becher teaches an advantageous method of applying actives to a carrier with greater control and versatility.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the active ingredients in a pattern. One would have been motivated to do so since Becher teaches that application in a pattern is preferred. There would be a reasonable expectation of success since applying the active in a pattern is well within in the scope, and is directly taught by, Becher.

It further would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the wafer shape of Becher for the invention of Suverkrup. One would have been motivated to do so since Suverkrup does not teach a specific shape, and Becher teaches that wafers are useful since they overcome technical difficulties previously seen in the art (see Becher, entire document, for instance, pages 2 and 3). There would be a reasonable expectation of success since Becher directly teaches the use of wafer.



**Claims 55 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suverkrup et al (U.S. Patent number 6,228,381, patent issued May 8, 2001) as applied to claims 23, 25, 27, 28, 40, 42-45, 48, 49, 54, and 57 above, and further in view of Wang et al (U.S. Patent number 5,166,058).**

The teachings of Suverkrup are set forth above.

Suverkrup, while teaching that proteins can be utilized (see entire document, for instance, column 6, line 19), fails to provide teaching with sufficient specificity.

Wang teaches the use of proteins as being useful as wound healing active agents (see for instance, Abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the protein of Wang as the active ingredient of Suverkrup. One would have been motivated to do so since Suverkrup teaches that the composition of Suverkrup is useful on wound surfaces, and Wang teaches that proteins are useful in wound healing. There would be a reasonable expectation of success since Suverkrup teaches that proteins can be utilized (see entire document, for instance, column 6, line 19).

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thornton*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**Claims 23, 25, 27, 28, 40, 42-45, 48, 49, 54-56, and 57 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22-25, 27-36, 39, and 43-45 of copending Application No. 11/661,726 in view of Suverkrup et al (U.S. Patent number 6,228,381, patent issued May 8, 2001).** Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claim recites a delivery system comprising a carrier, and active, obtainable by the method of claim 1 (namely said delivery system is a dried xerogel) which can be rehydrated, wherein the copending claims recite a dried xerogel comprising an active and carriers/excipients which can be rehydrated for use as a wound dressing.

The copending claims fail to directly recite that the composition has the active agent on at least one surface.

The teachings of Suverkrup are set forth above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to mix the active throughout the xerogel of the copending claims.

One would have been motivated to do so to allow for the active to be evenly dispersed and allow for even access and application of the active to the environment of use. There would be a reasonable expectation of success since the use actives mixed throughout a composition are well known.

For the above identified reasons, claims 23, 25, 27, 28, 40, 42-45, 48, 49, 54, and 57 are directed to an invention not patentably distinct from claims 22-25, 27-36, 39, and 43-35 of commonly assigned application 11/661,726.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 11/661,726, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

*Response to Arguments*

Applicant states in the remarks filed 01/27/2011 that Applicant believes the amendment have overcome the double patenting rejection. Applicant's argument is not found persuasive. See above rejection.

**Claims 38, 39, 41, 46, 47, 50-53, and 58-60 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22-25, 27-36, 39, and 43-45 of copending Application No. 11/661,726 in view of Suverkrup et al (U.S. Patent number 6,228,381) as applied to claims 23, 25, 27, 28, 40, 42-45, 48, 49, 54, and 57, and further in view of Becher (DE 19940241 translation attached and relied upon for citation – IDS reference).**

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claim recites a delivery system comprising a carrier, and active, obtainable by the method of claim 1 (namely said delivery system is a dried xerogel) which can be rehydrated, wherein the copending claims recite a dried xerogel comprising an active and carriers/excipients which can be rehydrated for use as a wound dressing.

The copending claims in view of Suverkrup fail to directly recite that the composition has the active agent on at least one surface in particular patterns and that the carrier is a certain shape.

The teachings of Suverkrup and Becher are set forth above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to mix the active throughout the xerogel of the copending claims. One would have been motivated to do so to allow for the active to be evenly dispersed and allow for even access and application of the active to the environment of use. There would be a reasonable expectation of success since the use of actives mixed throughout a composition are well known.

For the above identified reasons, claims 38, 39, 41, 46, 47, 50-53, and 58-60 are directed to an invention not patentably distinct from claims 22-25, 27-36, 39, and 43-35 of commonly assigned application 11/661,726.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 11/661,726, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were

commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

No claims allowed. All claims rejected. No claims objected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TREVOR LOVE whose telephone number is (571)270-5259. The examiner can normally be reached on Monday-Thursday 7:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TL  
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